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| THE PROCTER & GAMBLE COMPANY | | | SCHLIENTZ, NATHAN W | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/654,228 | HAYEK ET AL. | |
| | Examiner | Art Unit | |
| | Nathan W. Schlientz | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 April 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of Claims

Claim 2 has been cancelled and claim 1 has been amended in an amendment filed 03 April 2008. As a result, claim 1 is pending and thus examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Terminal Disclaimer

The terminal disclaimer filed on 03 April 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent No. 6,641,836 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,133,317 (Hart) in view of U.S. Patent No. 3,511,910 (Halleck).

Applicant claims:

Applicants claim a method for enhancing the immune response of a dog by feeding said dog a diet comprising about 1 to 10 g garlic, about 20 to 40 wt.% protein, about 4 to 30 wt.% fat, and about 1 to 11 wt.% fiber.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Hart teaches feeding a canine a diet comprising oxalic acid, crude protein, crude fat, crude fiber and moisture (Examples 119-121). Hart further teaches feeding 1 lb carrots, 1 lb parsley and 1 tsp garlic, a source of oxalic acid (col. 5, ll. 35-52), with 1 to 1½ lbs dry dog food (col. 16, ll. 11-15), which is approximately 2.6 to 4.4 g garlic per kg total dog food (see pages 4-5 of the office action mailed 16 April 2007). Hart also

teaches that garlic is believed to fight infection, cancer, bacteria, virus, and heart disease (col. 29, ll. 58-59).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Hart does not teach the amounts of protein, fat and fiber contained in the dry dog food fed in conjunction with the garlic. However, Halleck teaches that commercial dry dog food constituted the basal ration of 24% crude protein, 8% crude fat and 4.5% crude fiber.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use the commercial dry dog food taught by Halleck, which comprises 24% crude protein, 8% crude fat and 4.5% crude fiber, as the dog food mixed with 1 tsp of garlic per 1 to 1½ lbs dry dog food, as reasonably taught by Hart.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's Remarks filed 03 April 2008 have been fully considered but they are not persuasive. Applicants argue on page 4 that Hart fails to provide any guidance as

to an amount of garlic to administer to a dog for enhancing immune response in that dog. However, the examiner respectfully argues that Hart teaches administering approximately 2.6 to 4.4 g garlic per kg total dog food, as discussed above. Hart also teaches that garlic is believed to fight infection, cancer, bacteria, virus, and heart disease. Therefore, Hart teaches administering 2.6 to 4.4 g garlic per kg total dog food to fight infection, cancer, bacteria, virus and heart disease.

Applicant also argue on page 4 that the recitation by Hart of feeding a dog 1 lb. carrots, $\frac{1}{4}$ cup parsley, 1 tsp garlic and 1 to $1\frac{1}{2}$ lbs dry dog food, results in a dog food with three items listed by Hart as being sources of oxalic acid or oxalate, but Hart does not teach which of those sources is providing a beneficial effect. However, the examiner respectfully points out that Hart teaches that carrots, parsley and garlic are relatively high in oxalic acid or oxalate and should be eaten in order to build a high concentration of oxalic acid or oxalate in the body. Hart teaches that it is believed that if one can maintain a balanced diet and assure an adequate level of oxalic acid or oxalate in the system then the body's natural protection mechanisms, immune system, and the like can prevent, treat, and control tumors, growths, cancers, viral or bacterial diseases, chemical toxins, and the like (col. 29, ll. 46-55). Hart further teaches that garlic is believed to fight infection, cancer, bacteria, virus, and heart disease (col. 29, ll. 58-59). Therefore, Hart et al. clearly teaches that carrots, parsley, and garlic are all sources of oxalic acid which is believed to enhance the body's natural immune system. Hart even specifically states that garlic is believed to fight infection, cancer, bacteria, virus, and heart disease, which is an enhancement of immune response.

Applicants further argue on page 4 that Halleck fails to mention the use of garlic in a diet composition for a dog. However, the examiner relied on Halleck solely for the teaching that a commercial dry dog food comprises 24% crude protein, 8% crude fat and 4.5% crude fiber. Thus, Hart's teaching of mixing carrots, garlic, and parsley with dry dog food is relied upon for the teaching of adding garlic to a dog's dry food whereas Halleck is relied upon for the protein, fat and fiber content of the dry dog food.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

2. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,965,153 (Allen) in view of Hart and Halleck.

Applicant claims:

Applicants claim a method for enhancing the immune response of a dog by feeding said dog a diet comprising about 1 to 10 g garlic, about 20 to 40 wt.% protein, about 4 to 30 wt.% fat, and about 1 to 11 wt.% fiber.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Allen teaches feeding a dietary supplement to a dog comprising garlic, protein, fat and fiber (col. 2, ll. 8-30); wherein the supplement fosters healthy skin which includes

the reduction or elimination of occurrences of fungus infections and seasonal dry skin (col. 2, ll. 60-62). Allen further teaches that the dietary supplement is mixed with the animal's food once daily (col. 2, ll. 41-42).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Allen does not teach the specific amount of garlic used in the dietary supplement, which is effective at treating fungal infections. However, Hart teaches that approximately 2.6 to 4.4 g garlic per kg total dog food is sufficient to treat infections (col. 16, ll. 13-15; and col. 29, ll. 58-59).

Also, Allen does not teach the total protein, fat and fiber content of the dog food. However, Halleck teaches commercial dry dog food comprises 24% crude protein, 8% crude fat and 4.5% crude fiber.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use 2.6 to 4.4 g garlic per kg total dog food, as reasonably taught by Hart, in the dietary supplement as taught by Allen for fostering healthy skin by reducing or eliminating occurrences of fungus infections and seasonal dry skin. Furthermore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to mix the dietary supplement of Allen with commercial dry dog food comprising 24% crude protein, 8% crude fat and 4.5% crude fiber, as reasonably taught by Halleck.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on page 5 that Allen fails to teach a diet composition comprising 20-40% protein, 4-30% fat and 1-11% fiber, as well as any particular amounts of garlic.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Also, the examiner respectfully argues that Allen teaches administering garlic to reduce or eliminate incidences of fungal infections and seasonal dry skin. Hart teaches administering 2.6 to 4.4 g garlic per kg total dog food to fight infection, cancer, bacteria, virus and heart disease. Therefore, it would have been obvious to use 2.6 to 4.4 g garlic per kg dog food in the dog food of Allen, which is used to reduce infections and dry skin.

Applicant also argue on page 5 that it is not necessarily the case that by feeding any amount of garlic effective to reduce shedding one would intrinsically enhance the immune system. However, the examiner respectfully argues that Allen teaches

administering garlic to reduce or eliminate incidences of fungal infections, which is an enhancement of immune response; and Hart provide motivation for using 2.6 to 4.4 g garlic per kg total dog food to fight infection, cancer, bacteria, virus and heart disease. Therefore, it would have been obvious to use 2.6 to 4.4 g garlic per kg total dog food to reduce or eliminate incidences of fungal infection (i.e., enhance immune response) and seasonal dry skin.

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,976,549 (Lewandowski) in view of Hart and Halleck.

Applicant claims:

Applicants claim a method for enhancing the immune response of a dog by feeding said dog a diet comprising about 1 to 10 g garlic, about 20 to 40 wt.% protein, about 4 to 30 wt.% fat, and about 1 to 11 wt.% fiber.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Lewandowski teaches eliminating odors from a dog's breath by feeding raw garlic, which has been shown to lower blood pressure, reduce blood cholesterol, promote cardiovascular activity, soothe the respiratory system, relieve gas and indigestion, reduce yeast infections, and provide systemic insect repellent (col. 2, ll. 34-49), as well as killing odor-causing bacteria in the mouth (col. 4, l. 41). Lewandowski further teaches that it is preferred to mix uncooked garlic with a dog's food or snacks (col. 5, ll. 9-15).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Lewandowski does not teach the specific amount of garlic used to coat the dog's food, which is effective at lowering blood pressure, reducing blood cholesterol, promoting cardiovascular activity, soothing the respiratory system, relieving gas and indigestion, reducing yeast infections, and providing systemic insect repellent, as well as killing odor-causing bacteria in the mouth. However, Hart teaches that approximately 2.6 to 4.4 g garlic per kg total dog food is sufficient to fight infection, cancer, bacteria, virus, and heart disease (col. 16, ll. 13-15; and col. 29, ll. 58-59).

Also, Lewandowski does not teach the total protein, fat and fiber content of the dog food. However, Halleck teaches commercial dry dog food comprises 24% crude protein, 8% crude fat and 4.5% crude fiber.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use 2.6 to 4.4 g garlic per kg total dog food, as reasonably taught by Hart, in the coating of dog food as taught by Lewandowski for lowering blood pressure, reducing blood cholesterol, promoting cardiovascular activity, soothing the respiratory system, relieving gas and indigestion, reducing yeast infections, and providing systemic insect repellent, as well as killing odor-causing bacteria in the mouth. Furthermore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to mix the uncooked garlic of Lewandowski with commercial dry dog

food comprising 24% crude protein, 8% crude fat and 4.5% crude fiber, as reasonably taught by Halleck.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on page 6 that Lewandowski fails to teach a diet composition comprising 20-40% protein, 4-30% fat and 1-11% fiber, as well as any particular amounts of garlic. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Also, the examiner respectfully argues that Lewandowski teaches eliminating odors from a dog's breath by feeding raw garlic, which has been shown to lower blood pressure, reduce blood cholesterol, promote cardiovascular activity, soothe the respiratory system, relieve gas and indigestion, reduce yeast infections, and provide systemic insect repellent. Hart teaches administering 2.6 to 4.4 g garlic per kg total dog food to fight infection, cancer, bacteria, virus and heart disease. Therefore, it would have been obvious to use 2.6 to 4.4 g garlic per kg dog food in the dog food of

Lewandowki, which is used to lower blood pressure, reduce blood cholesterol, promote cardiovascular activity, soothe the respiratory system, relieve gas and indigestion, reduce yeast infections, and provide systemic insect repellent, because Hart teaches 2.6 to 4.4 g garlic per kg total dog food to fight infection, cancer, bacteria, virus and heart disease.

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,156,355 (Shields et al.) in view of Hart.

Applicant claims:

Applicants claim a method for enhancing the immune response of a dog by feeding said dog a diet comprising about 1 to 10 g garlic, about 20 to 40 wt.% protein, about 4 to 30 wt.% fat, and about 1 to 11 wt.% fiber.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Shields et al. teach dog formulations comprising at least 22 wt.% crude protein, at least 10 wt.% crude fat, at most 4 wt.% crude fiber, and garlic powder (Examples 1-5). Shields et al. further teach that garlic is thought to have some natural ability to inhibit growth of pathogenic organisms (col. 14, ll. 52-54).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Shields et al. do not teach the specific amount of garlic added to the dog food formulations, which is believed to inhibit growth of pathogenic organisms. However,

Hart teaches that approximately 2.6 to 4.4 g garlic per kg total dog food is sufficient to fight infection, cancer, bacteria, virus, and heart disease (col. 16, ll. 13-15; and col. 29, ll. 58-59).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use approximately 2.6 to 4.4 g garlic per kg total dog food, as reasonably taught by Hart, in the dog food formulations of Shields et al. in order to inhibit growth of pathogenic organisms.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on page 6 that Shields et al. do not provide any amounts or ranges of garlic in any of the disclosed compositions. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Also, the examiner respectfully argues that Shields et al. teach dog food compositions comprising protein, fat, fiber and garlic, and that garlic is thought to have some natural ability to inhibit growth of pathogenic organisms. Hart teaches administering 2.6 to 4.4 g garlic per kg total dog food to fight infection, cancer, bacteria, virus and heart disease. Therefore, it would have been obvious to use 2.6 to 4.4 g garlic per kg dog food in the dog food of Shields et al., which is thought to inhibit growth of pathogenic organisms, because Hart teaches 2.6 to 4.4 g garlic per kg total dog food to fight infection, cancer, bacteria, virus and heart disease.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616